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| CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10) | | | Docket No. 12.018011 | |
| Applicant(s): Hung | | | | |
| Application No. 09/912,499 | Filing Date 07/26/01 | Examiner Sirmons, Kevin, C. | Customer No. 0000 38732 | Group Art Unit 3763 |
| Invention: Methods and Devices for Diagnosis of Precancer and Cancer in Breast Milk Ducts | | | | |



I hereby certify that this **Request for Reconsideration of Office Action of February 22, 2005**
(Identify type of correspondence)

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
David HUNG) Examiner: Kevin C. Sirmons.
Serial No. 09/912,499) Group Art Unit: 3763
Filed: July 26, 2001) Attorney Docket No.: 12.018011
For: METHODS AND DEVICES FOR)
DIAGNOSIS OF PRECANCER)
AND CANCER IN BREAST MILK)
DUCTS)

REQUEST FOR RECONSIDERATION OF OFFICE ACTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

May 18, 2005

REMARKS

Status of the Claims

The Office Action of February 22, 2005 has been received and considered. No claim amendments have been made. Claims 1-8, 10-13, 26, and 27 remain pending. Reconsideration of the application in view of the following remarks is requested.

Withdrawal of Allowability of Claims 1 and 12

The Office Action of February 22, 2005 withdraws the allowability of claims 1 and 12. The Applicant respectfully submits that the withdrawal of allowability is inappropriate. The examiner has not cited any new art as the reason for the withdrawal of allowability, instead, the examiner states that the claims have been withdrawn because the examiner had a "change of interpretation of the claims". To support this change of interpretation, the examiner states that it

is his position that "...the probe of Pestes is rigid before entry into the breast duct because it will not unnecessarily bend before entry into the breast and yet it is ductile upon resistance to the duct". The examiner cites no part of Pestes that would suggest or teach that the probe is ductile depending upon the environment. Instead, it appears as if the withdrawal the allowability was based strictly upon the examiner's opinion that the probe in Pestes may assume this characteristic. This response is inappropriate and unfair to the Applicant.

The rejection of claims after allowance should not take place based upon the unsubstantiated opinion of an examiner. Great care should be exercised in authorizing such a rejection. See *Ex parte Grier*, 1923 C.D. 27, 309 O.G. 223 (Comm'r Pat. 1923); *Ex parte Hay*, 1909 C.D. 18, 139 O.G. 197 (Comm'r Pat. 1909). It is Applicant's position that the examiner has not met his burden of great care by the removal of allowability of claims without the citation of newly discovered art.

Not only has the examiner withdrawn the allowability of the claims, but he has reinstated the exact same rejections under 35 USC §102(b) (being unpatentable with respect to U.S. Pat. No. 5,623,942 to Pestes *et al.*), and under 35 USC §103(a) (being unpatentable over U.S. Pat. No. 5,623,942 to Pestes *et al.* in view of U.S. Pat. No. 4,616,656 to Nicholson *et al.*). These rejections were addressed previously in Applicant's amendment filed December 12, 2004. The rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) were withdrawn by the examiner in view of the Applicant's amendments to the claims. The Applicant respectfully argues that the rejection has already been successfully overcome by the previous amendment and that the claims should be allowed.

The Rejection Under 35 U.S.C. § 102 (a) Should Be Withdrawn

In the Office Action, claims 1-6 12 and 13 were rejected under 35 USC §102(b) as being unpatentable with respect to U.S. Pat. No. 5,623,942 to Pestes *et al.*

In the Office Action, it is asserted that the Patent to Pestes *et al.* discloses a flexible probe having a diameter sized to access a breast duct and a distal portion being capable of contacting an interior lumen of a breast duct and retrieving a sample of the breast duct fluid from within the duct for analysis. The examiner also states that the probe "...is rigid before entry into the breast duct, and flexible upon resistance into the duct..." (see page 2 of the Office Action). The Applicant respectfully disagrees.

The Patent to Pestes *et al.* does not contemplate a method or device that is composed of a material that is rigid in one state and flexible upon entry into a breast duct. Nowhere in Pestes *et al.* can the examiner point to such a statement or teaching. In the Office Action, the examiner points to certain paragraphs in the body of the Patent (col. 2, lines 16-25 and 32-40) as support for such a statement, however, no such description exists. In fact, as specifically stated in Pestes *et al.*, (see column 2 lines 32-33) the preferred material for the shaft of the probe is *fiberglass*. Fiberglass is highly non-flexible and certainly would not be ductile upon resistance to the duct.

Therefore, contrary to the position taken in the Office Action, the Patent to Pestes *et al.* does not disclose a flexible probe. Withdrawal of the rejection is requested.

The Rejection Under 35 U.S.C. § 103(a) Should Be Withdrawn

Claims 7-8, 10, 26 and 27 were rejected under 35 USC §103(a) as being unpatentable over U.S. Pat. No. 5,623,942 to Pestes *et al.* in view of U.S. Pat. No. 4,616,656 to Nicholson *et al.*

The patent to Nicholson *et al.* discloses a device and method for confirming the location of a presymptomatic, non-palpable breast lesion by placement and manipulation of a probe. The probe is comprised of a cannula housing a wire. The wire is percutaneously introduced into the fleshy sidewall of a breast whereat it is hoped the distal end lies at about 2 cm from a lesion previously determined by a mammography. The percutaneously inserted probe wire remains as a location marker for invasive surgical excision of the lesion. Also, the percutaneously inserted wire is coated with a silicone or Teflon for purposes of lubricity and electrical insulation.

The examiner states that "...it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the distal portion of Pestes with the means to measure a quality of the ductal fluid as taught by Nicholson for providing markings to indicate the depth of the device distal end when anchored." (see page 3). The Applicant respectfully disagrees.

The marker described in Nicholson *et al.* is not for determining the quality of ductal fluid. As mentioned previously, the wire probe in Nicholson *et al.* is a location marker for invasive surgical excision of the lesion. There is absolutely no description or teaching in Nicholson *et al.* of a marker for the qualitative analysis of any bodily fluid. The examiner has apparently mistaken qualitative analysis for quantitative analysis. Examples of qualitative analysis can be, for example, cell size, cell density, nuclear size, nucleoli size, and chromatin coarseness.

Thus, Applicant submits that neither the Patent to Pestes *et al.*, nor the Patent to Nicholson *et al.* either alone or in combination, anticipates the claimed subject matter of the present invention.

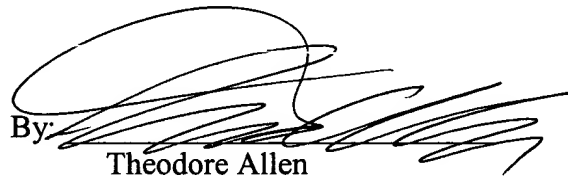
CONCLUSION

For all of the above-discussed reasons, Applicant respectfully submits that claims 1-8, 10-13, 26 and 27 are allowable and that the application is now in condition for allowance. A notice to this effect is earnestly solicited. It is believed that no fee is required for this submission. If any fees are required or if an overpayment is made, the Commissioner is authorized to debit or credit our Deposit Account No. 502855, accordingly. If any questions or issues remain, the resolution of which the Examiner feels would be advanced by a conference with Applicant, the Examiner is invited to contact Applicant's attorney at the number noted below.

Respectfully submitted,

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